STATE MEDICAID DUR BOARD MEETING

THURSDAY, October 9, 2008
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:

Mark Balk, PharmD.
Neal Catalano, R.Ph.
Joseph Miner, M.D.
Colin Vanorman, M.D.
Peter Knudson, DDS
Wilhelm Lehmann, M.D.
Tony Dalpiaz, PharmD.
Bradford Hare, M.D.

Board Members Excused:

Joseph Yau, M.D.
Bradley Pace, PA-C
Derek Christensen, R.Ph.

Dept. of Health/Div. of Health Care Financing Staff Present:

Jennifer Zeleny
Lisa Hulbert
Rick Sorensen, RN
Carol Runia
Tim Morley
Duane Parke
Merelynn Berrett, R.N.

Other Individuals Present:

Craig Boody, Lilly
Ann Gustafson, GSK
Adam Westover, Pfizer
Emily Trone
Robert F. Miller
Tim Smith, Pfizer
Michael Measom, M.D.
Candi Acree Larreta, Pfizer
Shelby Fletcher, Pfizer
J. Gaustad, Purdue
Joanne LaFleur, U of U
Tamara Lewis, M.D. (IHC)
Don McNeal, Elan
Alan Bailey, Pfizer
Ben Focht, Amylin
Reed Murdoch, Wyeth
Shannon Hern, GSK

Meeting conducted by: Colin VanOrman, M.D.

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1. Minutes for September 11, 2008 were approved. The motion to approve the minutes was made by Dr. Knudson and seconded by Dr. Hare. The minutes were unanimously approved by Dr. Knudson, Dr. Hare, Neal Catalano, Dominic DeRose, Dr. Miner, and Dr. VanOrman.

2. Oxycodone SA Milligram Limits for Non-malignant Pain: Emily Trone and Ann Lingard from the University Of Utah College Of Pharmacy addressed the Board. Utah Medicaid currently has a limit on the opioid products and combination products of 180 units per 30 days, the lollipops and effervescent have a limit of 120 units in 30 days (for cancer diagnoses only), the long acting products have a limit of 90 units in 30 days, and the fentanyl patches have a limit of 15 units in 30 days. All of these limits are overridden with a cancer diagnosis. In the past, the question of the possibility of daily milligram limits has arisen. The computer programming possibilities have

been researched; Tim Morley and Jennifer Zeleny can answer questions about that. Currently, the concern with the monthly cumulative limits is that a patient can get up to 80mg TID of long-acting oxycodone, so it doesn't really focus the limit to a safer dose. They tried to research if there is a logical daily milligram limit for oxycodone. The number of 120mg daily milligrams came up from various providers in the community, so they tried to research whether or not there was a good basis for this limit. There is not very much evidence for or against this limit in the medical literature. They found two articles that summarized the evidence available for the treatment of non-malignant pain. Most of the trials did not use very high doses, and introduced the concept of morphine equivalence. Most of the trials did not use above 180mg of morphine equivalents per day. The trials are not very long either; the longest was 32 weeks. There was one set of guidelines put out by Washington State that recommended that doses above 120mg of morphine equivalents per day should not be prescribed without a pain consultation. The next resource reviewed was statements from various providers. They consulted with Dr. Fakata, PharmD from Lifetree Pain clinic. She did not feel that there was a logical limit; her response was provided to the Board. The providers at this clinic do not use a protocol in titration, and try to individualize treatments for patients. Dr. Lipman from the College of Pharmacy who is a pain specialist at Red Butte Clinic does use a titration protocol. He uses two 50% increases for a patient based on response. His typical maximum dose under this protocol would be 130mg.

Tim Morley asked if Dr. Fakata was aware that that she was being asked specifically about treatment of non-malignant pain. She was aware.

Dr. Hare stated that the vast majority of care at Lifetree Pain Clinic is provided by nurse practitioners rather than physicians. Their system for treating patients is different. Dr. Hare stated that if Medicaid wants to place absolute limits, 120mg per day is not appropriate. For most patients, 120mg of oxycodone per day, even in his specialty practice, is a good threshold and anything above that probably needs some scrutiny. It is unusual for patients to need higher doses than this. When the initial limits were set, the physician was asked to complete a simple one-page form asking basic questions about the patient's treatment plan to seek an override to the limits.

Tim Morley stated that the information packet includes a list of a year's worth of claims data indicating how many patients received greater than 120mg per day. Mark Balk indicated that there are some inaccuracies in this packet.

Dr. Miller addressed the Board. Dr. Miller works part time for the Health Clinics of Utah. People arrive from all over the country on extremely high doses of opioids, and he is faced with having to taper them off. The maximum limit is already on the patients when they walk through the door, and the next issue is to determine how quickly they can be tapered off. The incidence of new prescriptions for his practice is fairly low, probably around 5%.

Tim Morley stated that this particular question has been brought forward by several practitioners, particularly in light of the environment they are in today. There is an increased level of scrutiny on opioid use in the State of Utah. The current limits in place are quantity limits on tablets, which can create a wide variety of possibilities of doses. It also creates some problems for Medicaid. Before intermediate dosage strengths of Oxycontin were introduced, Medicaid has had to override quantities to get patients to intermediate doses (i.e. 90 x 20mg and 90 x 40mg to achieve a 60mg dose). Also, it creates a hassle when titration overrides for lower strengths are needed. Medicaid has now found out how to be able to program calculations based on maximum daily milligram limits, and would like to explore the possibility of milligram-driven limits as a rational approach.

The Board stated that they liked the idea of letting Medicaid be the "bad guy" in imposing limits to drive more rational prescribing in the community. Dr. Hare stated that many clients come to his clinic on high doses of Oxycodone. These drugs are rarely indicated at high doses for long-term management of chronic pain. Many times his clinic is faced with getting patients off inefficacious high doses of opioids in addition to trying to find a more rational treatment approach to their pain. He would not want to place limits that would create problems for his practice, but he rarely sees patients that would need to be on such high doses.

Tim Morley stated that many of these drugs are indicated for BID doses, but they are not used this way. Dr. Hare disagreed and stated that the BID claim seems to be exaggerated for marketing purposes. This is also the case with many of the drugs that are indicated for daily dosing.

Dr. Miner stated that he would be comfortable with 120mg per day. Many people would need to be tapered down quickly, but that is not necessarily bad, and 120mg per day is still a fairly high dose.

Dr. Hare asked if it is even possible for a Medicaid client to have a chronic pain consultation. In the past it was a problem to have this service paid. Tim Morley stated that this is still being worked on.

Duane Parke stated that short-acting formulations are often prescribed for breakthrough pain. Even with limits placed on the long-acting formulations, patients can still receive short-acting formulations as a backup.

Dr. Hare stated that other long-acting products should be considered for discussing limits while oxycodone is being considered. Oxycodone has the worst reputation and receives the worst press, but logical limits can be placed on the whole group.

Dr. Lehmann asked how new limits would be communicated to the patients. Medicaid can use the Amber Sheet, MIB, and patient-specific letters. Medicaid could also notify the individual pharmacies prior to new limits going into place. When the current limits went into place, Medicaid worked 6 months in advance of the limits in providing notification. Approximately

2,000 patients would need to be notified of the reduction of benefits.
The Board stated that short-acting opioids should be included in daily milligram limits. If long-acting opioids are reduced, short acting opioids could be increased. This would not decrease the total opioid burden, and may provide a poor standard of care.

Dr. Hare moved that Medicaid look at all of the long-acting opioids and return with a policy recommendation for daily milligram limits on all opioids, taking into account the milligrams of short-acting opioids in addition to the long acting ones. He offered to assist Medicaid in formulating such a proposal. Dr. Miner seconded the motion. The motion was unanimously approved by Dr. Knudson, Dr. Hare, Neal Catalano, Dominic DeRose, Dr. Miner, Mark Balk, Tony Dalpiaz, Dr. Lehmann, and Dr. VanOrman.

3. Relistor: Tim Morley addressed the Board. Relistor, methylnaltrexone, is a new product on the market that is FDA approved for opioid induced constipation in patients with advanced illness in palliative care when response to laxatives has not been sufficient. The Board was provided with handouts from the FDA on Relistor. It is contraindicated in patients with known or suspected mechanical GI obstruction. Duration of use has not been studied for longer than 4 months, and it has not been studied in patients with peritoneal catheters. This medication appears to be very effective in overcoming opioid-induced constipation, but it has some fairly significant limits in terms of FDA approval. The Department seeks to limit its use to those restrictions, simply because it would not be wise to have this fall into the first-line treatment choice for even opioid-induced constipation.

Duane Parke stated that the studies show that it only works in 50% of the cases at all. There are patients that it does not work for.

The Board asked about administration. It is administered subcutaneously.
The Board asked if there are any suspicions that this drug will be overused. This agent is very new on the market, so there is no way to tell how much it will be used.

Dr. Hare stated that he does not believe that there will be any desire for people to abuse this, since it is a pure opioid receptor antagonist and probably does not cross the blood-brain barrier.

The Board felt that this drug would not benefit patients with any condition other than opioid-induced constipation, but thought that it might become attractive to GI doctors dealing with chronic constipation that are running out of options.

Tim Morley stated that this is indicated for patients receiving palliative care, so it should really only be an option for patients who have progressed fairly significantly in their illness and treatment with opioids. Medicaid wants to make sure that all other options for laxatives are exhausted within this population before Relistor is tried.

The Board asked about the cost. Medicaid cannot discuss the cost during the discussion about the PA. It can be discussed after the PA vote has been taken.

Dr. Miller addressed the Board. He stated that for gastroenterologists the usual problem is the initial treatment. Short-term use of this particular drug may be beneficial to restore normal bowel function that would then respond to conventional laxatives.

Dr. Miner asked if it is possible to program the system in such a way that an initial dose will go through the system, and require a PA for ongoing use. Tim Morley stated that this would require extensive programming and is not practicable. Dr. Hare felt that a PA for all clients would be appropriate.

Dr. Hare stated that the FDA approval for this drug was only for chronic opioid patients receiving palliative care. However, not all chronic opioid patients are receiving palliative care. These patients could receive the drug off-label.

Dr. Miner moved that the proposed PA criteria that are in line with the FDA labeled indication are accepted. Dr. Hare seconded the motion. The motion was unanimously approved by Dr. Knudson, Dr. Hare, Neal Catalano, Dominic DeRose, Dr. Miner, Mark Balk, Tony Dalpiaz, Dr. Lehmann, and Dr. VanOrman.

4. Chantix PA Review: Tim Morley addressed the Board. Chantix is currently on PA and this is the follow-up review. The University was asked to prepare a criteria review for smoking deterrents as a group. The information is not available for this meeting, but Medicaid is planning on having this information at a future meeting for a larger discussion on the class, and Chantix should be a part of that larger discussion. Therefore it will be brought in 2 parts. Today the Board can hear the available information on Chantix and table a decision until the larger discussion can be held.

Dr. Tamara Lewis, Medical Director for Community Health and Prevention at Intermountain Healthcare addressed the Board representing the 600 physicians of the Intermountain Healthcare Medical Group. She presented handouts to the Board. In terms of tobacco, she is the Medical Advisor for the Coalition for Tobacco in Utah. She is on the Advisory Board for the Tobacco Prevention and Control Program at the Department of Health. Over the last 10 years, besides working with the medical group trying to encourage physicians to do appropriate tobacco therapy, she has worked with Select Health to develop programs for patients. One of the things she has done is develop cost models to show whether this is a cost-effective program or not. Each of the various programs offered over the years has been analyzed. Varenicline has been on the formulary since 2006, and last year was moved from a tier 3 up to a tier 2 based on efficacy and cost. She has concluded that this therapy and the other therapy available for smoking cessation do save lives. In the last 10 years, IHC has had 7500 people quit long-term, which has equated out to 3000 lives that would have been lost due to tobacco. The

quit rate with varenicline has been extremely impressive and is factored into these models. The key inputs that one wants to look at are the cost of the program versus the cost savings seen over time for individuals. The specific cost savings that have been used have come from the CDC. The CDC says that about $1600 will be saved per year for an individual who quits. IHC has been even more conservative and used ¼ of this figure, which comes from Milliman and Robertson estimated by looking at large health plans throughout the country. IHC has found that over a 10 year cost model there is a return on investment and a high net present value. IHC has concluded that they do make money by providing this service. If a program makes money by enrolling patients, it will make even more money if more patients are enrolled. In order to make even more money, the program has to have a high retention rate. IHC has an approximately 85% retention rate for the smokers it has enrolled in its quit programs per year. The State has a 2% attrition rate. If Medicaid has a high retention rate for smokers that it has invested in, it will have an even higher return rate by retaining them in a quit program. IHC has seen a net present value of bupropion at $670,000 over 10 years when it was in its higher-cost version of Zyban. IHC has estimated double that net present value with varenicline as the cost analysis is conducted. This is based on the interest in varenicline. It is an easy medication to take, has a support system behind it, and a high quit rate. The high quit rate is the key factor in the model that is showing a high net present value benefit. The other thing seen is that the time should not be restricted in the early months of a patient attempting to quit. Some people may stop and start during the first 3 months. The higher success rates are seen at 6 and 12 months. IHC believes that patients should be allowed to have a longer course of therapy, and should be allowed to have multiple attempts at therapy. Most smokers have been through multiple quit attempts throughout their lifetime. Having a once per lifetime benefit excludes these individuals who have a high probability of quitting the next time. She is willing to assist Medicaid in using its own data in IHC's cost model to determine how removing barriers to varenicline can benefit Medicaid. Physician incentives can also assist Medicaid with enrolling more clients in a quit program.

Duane Parke asked if this is prescribed on a chronic ongoing basis for Select Health clients. Select Health clients receive one 6 month therapy per year.

The Board asked if the lifetime benefit should be removed from Chantix. Dr. Lewis stated that she did not see a reason to have the one course per lifetime criteria, since the only indications are that the patient be 18 years old and a smoker. Select Health does not have a problem with physicians treating clients under 18 with this drug.

Tim Morley stated that the State Plan only allows Medicaid to cover smoking cessation as long as the tobacco settlement money is available. Medicaid does not have funds out of the regular appropriation available for smoking cessation. Smoking cessation is an option program under federal law, and Medicaid is only paying it because the settlement funds are available. The federal program requires Medicaid to consider all therapies and options. Lower cost alternatives must be considered.

Dr. Lewis stated that Select Health has approximately 15 years of MSA funds left. Select Health also believes that a cadre of therapies should be available for smoking cessation, including bupropion, telephone quit lines, nicotine replacement, and varenicline. Select Health has seen that there are higher quite rates with varenicline.

Dr. Michael Measom addressed the Board. He is an addiction psychiatrist. There are 3 certified addiction psychiatrists in the State of Utah, and he is certified by the American Society of Addiction Medicine. Prior to moving to Utah, he worked in a smoking cessation clinic for 8 years. This was prior to Chantix being available. Tobacco dependence is the leading cause of death in the United States. It causes more death than drugs, car accidents, alcohol, firearms all added together. It shortens a person's life by 15 years. There are huge healthcare costs, both primary and secondary, from tobacco. Tobacco is by far the most addictive substance out there. He spends his time treating people with addiction, and knows that it is not viewed as a chronic relapsing medical condition, which it is. Moreover, nicotine use and tobacco dependence increases the rate of relapse for other substances, so there is a cost savings there. When he talks to his patients about Chantix, he talks to them about the part of the brain that says "NO", but that the deeper structures of the brain that drive craving and urges saying "YES". The movement in all treatments is towards biological treatments. If a patient can have both behavioral and biological treatments, their outcomes are much better. He feels that Chantix is a psychiatric medication, and should be treated that way in terms of what has gone on recently with the legislature. The parity law was just passed for mental health at the national level, for both psychiatry and addiction. His biggest issue is that this is a chronic relapsing medical condition, and he feels that once per lifetime is biased, discriminatory, and not helpful for someone who has this condition. Chantix is almost twice as effective as everything else that is out there. They actually offer behavioral treatment with their prescriptions. He brought a cost-benefit analysis conducted at the University of Utah and distributed it to the Board. He also provided a letter to the Board from a patient who would like to have more opportunities to use Chantix, as it had helped her to quit in the past.

Dr. Miner felt that the PA should be removed from Chantix. There should not be barriers for a smoking cessation product that is more effective than any other thing available.

Tony Dalpiaz stated that people call him for Chantix refills when they get the urge to smoke, and use it as a PRN pulse therapy. If this becomes a trend, patients could start to use it PRN for the rest of their lives. This is concerning, since there is no data to support this kind of use.

The Board asked how the tobacco settlement money distribution worked, and if there was an annual cap. There is no annual cap. The only cap is that when the settlement money is gone, the program will end. Medicaid currently pays for the claims and then bills the area of the Department of Health that administers those funds. Medicaid does not know when the money will run

out, but will probably cease to be able to bill the claims when the money runs out. This is in the State Plan, which is required by CMS to be filed. Medicaid must abide by this State Plan, which excludes drug classes such as smoking cessation and weight loss. The current State Plan only makes a provision for paying for smoking cessation as long as the settlement money is available. This was enacted at the policy level through Medicaid.

Mark Balk stated that he thinks that CMS has, in the last year, recommended and allowed coverage for smoking cessation. The rule that Medicaid is working under may be dated. Many states are now choosing to pay for it. Tim Morley clarified that this is still an optional service. Utah Medicaid still has not chosen to pay for smoking cessation this way because the tobacco settlement money is still available and reimbursement can continue through this route. He again suggested that an overall decision be delayed until the University of Utah can provide the smoking cessation review.

Dr. Miner moved to remove the PA off Chantix. Dr. Lehmann seconded the motion. The motion was approved with votes by Dr. Knudson, Neal Catalano, Dominic DeRose, Dr. Miner, Mark Balk, Dr. Lehmann, and Dr. VanOrman. Tony Dalpiaz opposed the motion.

Next meeting set for November 11, 2008
Meeting adjourned.

The DUR Board Prior Approval Subcommittee considered one petition this month.

Minutes prepared by Jennifer Zeleny